

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>PRD2076f-PCT-USA</b>
INTERNATIONAL APPLICATION NO. <b>PCT/EP2004/051048</b>	INTERNATIONAL FILING DATE <b>7 June 2004</b>	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/560476</b> PRIORITY DATE CLAIMED <b>10 June 2003</b>
TITLE OF INVENTION <b>NOVEL FORMULATIONS OF OPIOID-BASED TREATMENTS OF PAIN COMPRISING SUBSTITUTED 1,4-DI-PIPERIDIN-4-YL-PIPERAZINE DERIVATIVES</b>		
APPLICANT(S) FOR DO/EO/US <b>Frans Eduard Janssens, Francois Maria Sommen, Benoit Christian Albert Chislain De Boeck, Joseph Elisabeth Leenaerts, Yves Emiel Maria Van Roosbroeck, and Theo Frans Meert</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))               <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).               <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))               <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>		
Items 11 to 20 below concern document(s) or information included:		
<ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A preliminary amendment.</li> <li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</li> <li>18. <input checked="" type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> </ol>		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <div style="font-size: 2em; font-weight: bold; text-align: center;">10/560476</div>		INTERNATIONAL APPLICATION NO. PCT/EP2004/051048		ATTORNEY'S DOCKET NUMBER PRD2076f-PCT-USA	
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20. Other items or information:  
**Published Application WO 2004/110415 A2 and A3 w/Search Report Attached**  
**Power of Attorney for Each Inventor (6)**  
**Express Mail Certificate**

The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21.	<input checked="" type="checkbox"/>	Basic national fee (37 CFR 1.492(a)).....	\$300	\$ 300.00	
22.	<input checked="" type="checkbox"/>	Examination fee (37 CFR 1.492(c))		\$ 200.00	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....				\$ 0	
All other situations.....				\$200	
23.	<input checked="" type="checkbox"/>	Search fee (37 CFR 1.492(b))		\$ 400.00	
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....				\$ 0	
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....				\$100	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....				\$400	
All other situations.....				\$500	
<b>TOTAL OF 21, 22 and 23 =</b>				<b>900.00</b>	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$ 0.00	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	17 - 20 =	0	x \$ 50	\$ 0	
Independent claims	3 - 3 =	0	x \$200	\$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$ 0	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$ 900.00</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
<b>SUBTOTAL =</b>				<b>\$ 900.00</b>	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$ 0.00	
<b>TOTAL NATIONAL FEE =</b>				<b>\$ 900.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ 0.00	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$ 0.00</b>	
				Amount to be refunded:	\$
				Amount to be charged	\$

10/560476  
IAPS Rec'd PCT/PTO 12 DEC 2005

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 10-0750 in the amount of \$ 900.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 10-0750. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Hal B. Woodrow, Esq.  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933  
U.S.A.

Hal B. Woodrow  
SIGNATURE

Hal B. Woodrow  
NAME

32,501  
REGISTRATION NUMBER

10/560476  
IAGS Rec'd PCT/PTO 12 DEC 2005

Docket No. PRD2076f-PCT-USA

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Frans Eduard Janssens et al.

For: NOVEL FORMULATIONS FOR OPIOID-BASED TREATMENTS OF PAIN  
COMPRISING SUBSTITUTED 1,4-DI-PIPERIDIN-4-YL-PIPERAZINE  
DERIVATIVES

Express Mail Certificate

"Express Mail" mailing number: EV 368 590 025 US

Date of Deposit: December 12, 2005

I hereby certify that this entry into the National Phase pursuant to 35 USC 371 contains complete application:

<input checked="" type="checkbox"/>	Express Mail Certificate	(1 page)
<input checked="" type="checkbox"/>	Return Receipt Postcard	(1 page)
<input checked="" type="checkbox"/>	PCT FORM 1390 Transmittal	(3 pages)
<input checked="" type="checkbox"/>	Copy of International Application as filed	(83 pages)
<input checked="" type="checkbox"/>	Declaration of Inventors	(4 pages)
<input checked="" type="checkbox"/>	Power of Attorney for Inventors	(6 pages)
<input type="checkbox"/>	Assignment & Recordal Cover Sheet	(2 pages)
<input checked="" type="checkbox"/>	Preliminary Amendment	(9 pages)
<input checked="" type="checkbox"/>	WO 2004/110415 A2 & A3	(45 pages)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee; service under 37 CFR 1.10 on the date indicated above is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450..

Laurie Phillips

(Typed or printed name of person mailing paper or fee)

/Laurie Phillips/

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